

## **PCT**





Applicant's or	agentia fila reference	<u> </u>	
PC5953/20	agent's file reference 132	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International a	pplication No.	International filing date (day/month)	/year) Priority date (day/month/year)
PCT/IB01/0	00026	11/01/2001	25/01/2000
International P C07C59/12	atent Classification (IPC) or nat	tional classification and IPC	
Applicant			
WARNER-L	AMBERT COMPANY et	al.	
	rnational preliminary examinansmitted to the applicant a		by this International Preliminary Examining Authority
2. This REI	PORT consists of a total of	4 sheets, including this cover sh	eet.
beei	n amended and are the bas	•	e description, claims and/or drawings which have ontaining rectifications made before this Authority ns under the PCT).
These a	nnexes consist of a total of	sheets.	
3. This repo	ort contains indications relat	ting to the following items:	
ı	☐ Basis of the report		
11 [	☐ Priority		
)III [		pinion with regard to novelty, inve	entive step and industrial applicability
IV [	Lack of unity of invention		
V (		der Article 35(2) with regard to n	ovelty, inventive step or industrial applicability;
VI [	☐ Certain documents cite	d	
VII [	$\Box$ Certain defects in the in	ternational application	
VIII [	Certain observations on	the international application	
Date of submis	ssion of the demand	Date of co	ompletion of this report
10/05/2001		27.03.200	02
preliminary exa	ling address of the international amining authority:	Authorize	d officer
<i>o</i> ))) □	uropean Patent Office -80298 Munich el. +49 89 2399 - 0 Tx: 523656	Janus, S	S (LILAND STATE OF THE STATE OF
	ax: +49 89 2399 - 4465	· I	e No. +49 89 2399 8333

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB01/00026

I.	Bas	sis of the reprt	
1.	the and	receiving Office in	ments of the international application (Replacement sheets which have been furnished to response to an invitation under Article 14 are referred to in this report as "originally filed" to this report since they do not contain amendments (Rules 70.16 and 70.17)):
	1-3	8	as originally filed
	Cla	ims, No.:	
	1-5	1	as originally filed
	Dra	wings, sheets:	
	1/2	7-27/27	as originally filed
2.			guage, all the elements marked above were available or furnished to this Authority in the international application was filed, unless otherwise indicated under this item.
	The	se elements were a	available or furnished to this Authority in the following language: , which is:
		the language of a	translation furnished for the purposes of the international search (under Rule 23.1(b)).
		the language of pu	ublication of the international application (under Rule 48.3(b)).
		the language of a 55.2 and/or 55.3).	translation furnished for the purposes of international preliminary examination (under Rule
3.			eleotide and/or amino acid sequence disclosed in the international application, the y examination was carried out on the basis of the sequence listing:
		contained in the in	ternational application in written form.
		filed together with	the international application in computer readable form.
		furnished subsequ	ently to this Authority in written form.
		furnished subsequ	ently to this Authority in computer readable form.
			t the subsequently furnished written sequence listing does not go beyond the disclosure in oplication as filed has been furnished.
		The statement tha	t the information recorded in computer readable form is identical to the written sequence rnished.

☐ the description,

☐ the claims,

4. The amendments have resulted in the cancellation of:

pages:

Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB01/00026

		the drawings,	sheets:		
5.		*		-	ome of) the amendments had not been made, since they have been as filed (Rule 70.2(c)):
		(Any replacement she report.)	eet contai	ning such	amendments must be referred to under item 1 and annexed to this
6.	Add	litional observations, if	necessar	r <b>y</b> :	
V.		soned statement und tions and explanation		• •	ith regard to novelty, inventive step or industrial applicability;
1.	Stat	ement			
	Nov	relty (N)	Yes: No:	Claims Claims	
	Inve	entive step (IS)	Yes: No:	Claims Claims	28-41
	Indu	ustrial applicability (IA)	Yes: No:	Claims Claims	1-45, 48 46, 47, 49-51

2. Citations and explanations see separate sheet

#### Concerning S ction V

1. WO-A-99/30704 (D1) discloses (see in particular example I) the use of a pharmaceutical composition comprising the calcium salt of atorvastatin and the calcium salt of 6, 6'-oxybis-(2,2-dimethylhexanoic acid), also named CI-1027. It is also said in D1 (see p. 7, line 8) that the compounds of formula III (to which CI-1027 belongs) may occur as hydrates or solvates.

It is therefore considered that the skilled person would have, after reading D1, seriously contemplated preparing the present compounds of formula (II), in all possible crystal forms.

For these reasons, the subject-matter of present claims 1-27 and 42-51 is regarded as anticipated by D1 (Art. 33.2 PCT).

2. D1 does not specify how said compound CI-1027 is actually prepared. However, D1 does describe generally (see p. 7, lines 4-6) the preparation of "pharmaceutically acceptable" salts by neutralisation of the free acid in a cosolvent, concentration (i.e. solvent evaporation) being mentioned as a possible isolation procedure. The process claimed in present claims is therefore regarded as one of very few possibilities the skilled person would have selected from in order to prepare the compounds of D1, without having to exercise any sort of inventive activity.

The subject-matter of present claims 28-41 must therefore be regarded as lacking inventive step.

3. For the assessment of the present claims 46, 47 and 49-51 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.



#### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PC5953/20132	FOR FURTHER see Notification (Form PCT/ISA/	of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/IB 01/00026	11/01/2001	25/01/2000
Applicant WARNER-LAMBERT COMPANY e	t al.	
according to Article 18. A copy is being  This International Search Report consis		
language in which it was filed, ι	ne international search was carried out on the ba unless otherwise indicated under this item.	
Authority (Rule 23.1(b))		
was carried out on the basis of contained in the interna	the sequence listing : ational application in written form.	nternational application, the international search
furnished subsequently	nternational application in computer readable for to this Authority in written form.	m.
the statement that the s	to this Authority in computer readble form.  subsequently furnished written sequence listing of	does not go beyond the disclosure in the
	n as filed has been furnished. nformation recorded in computer readable form	is identical to the written sequence listing has been
2. X Certain claims were fo	ound unsearchable (See Box I).	
3. Unity of invention is I		•
4. With regard to the title,	I to the second	
l ————————————————————————————————————	submitted by the applicant.  Dished by this Authority to read as follows:	
5. With regard to the abstract,		
the text is approved as	submitted by the applicant. lished, according to Rule 38.2(b), by this Author the date of mailing of this international search re	rity as it appears in Box III. The applicant may, port, submit comments to this Authority.
6. The figure of the <b>drawings</b> to be page	ublished with the abstract is Figure No.	
as suggested by the ap		None of the figures.
I =	failed to suggest a figure. ter characterizes the invention.	

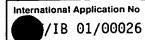


pternational application No. PCT/IB 01/00026

Box I	Observations where certain claims were found unsearchable (C ntinuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
	Although claims 46, 47 and 49-51 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound.
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inte	ernational Searching Authority found multiple inventions in this international application, as follows:
	Tananan menganan men
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
	~ <del></del>
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark	con Protest The additional search fees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search fees.

#### INTERNATIONAL SEARCH REPORT





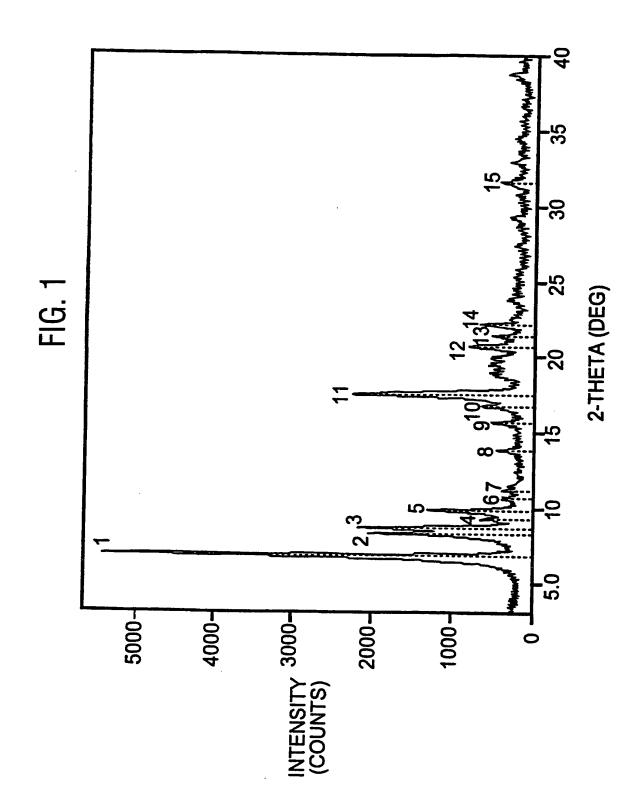
A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C07C59/125 A61K31/19 A61P3/10	
According to International Patent Classification (IPC) or to both national classifica	tion and IPC
B. FIELDS SEARCHED	
Minimum documentation searched (classification system followed by classification IPC 7 C07C A61K	on symbols)
Documentation searched other than minimum documentation to the extent that so	
Electronic data base consulted during the international search (name of data base EPO-Internal, WPI Data, PAJ, CHEM ABS Data	
LFO-Internat, Wil Baca, 1710, Chen, 180	
C. DOCUMENTS CONSIDERED TO BE RELEVANT	
Category ° Citation of document, with indication, where appropriate, of the rele	evant passages Relevant to claim No.
WO 99 30704 A (WARNER LAMBERT CO CHARLES LARRY (US); NEWTON ROGER 24 June 1999 (1999-06-24) page 7, line 4 - line 8; example	SCHOF)
A WO 96 30328 A (WARNER LAMBERT CO) 3 October 1996 (1996-10-03) page 11, line 1; claim 9; example 8 US 5 648 387 A 15 July 1997 (19) cited in the application	e 1
Further documents are listed in the continuation of box C.	X Patent family members are listed in annex.
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another	<ul> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance; the claimed invention</li> </ul>
citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means  "P" document published prior to the international filing date but later than the priority date claimed	cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
15 March 2001	2 8. 03. 01
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Janus, S

#### INTERNATIONAL SEARCH REPORT

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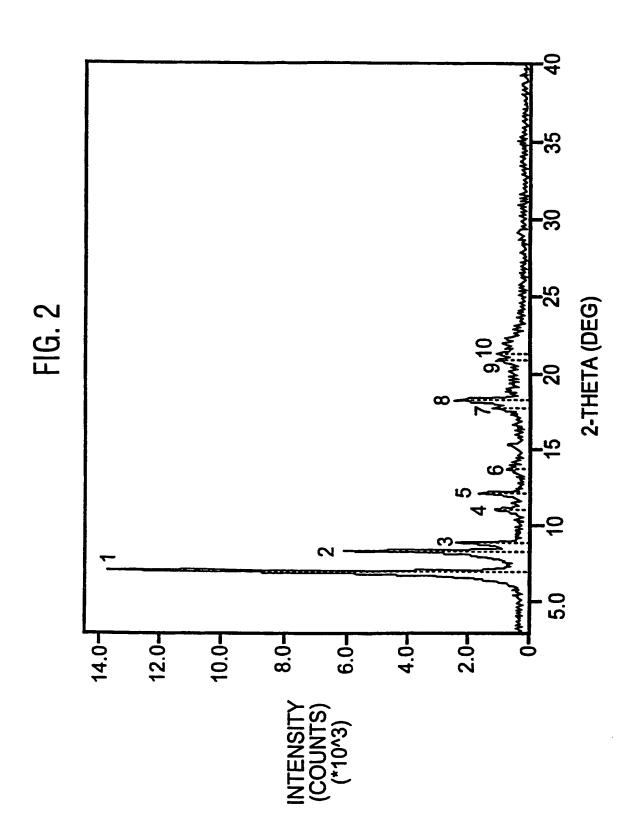
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9930704 A	24-06-1999	AU 1591599 A BR 9813542 A EP 1045691 A NO 20002966 A ZA 9811348 A	05-07-1999 10-10-2000 25-10-2000 09-06-2000 14-06-1999
W0 9630328 A	03-10-1996	US 5648387 A AT 192732 T AU 692359 B AU 4776896 A BG 101993 A CA 2215233 A CN 1182415 A CZ 9702922 A DE 69608268 D DE 69608268 T EP 0820428 A ES 2148733 T FI 973713 A HU 9801825 A JP 11502532 T NO 974397 A NZ 302170 A PL 322407 A PL 322407 A PT 820428 T SI 820428 T	15-07-1997 15-05-2000 04-06-1998 16-10-1996 29-05-1998 03-10-1996 20-05-1998 14-10-1998 15-06-2000 09-11-2000 28-01-1998 16-10-2000 24-09-1997 28-12-1998 02-03-1999 20-11-1997 29-04-1999 19-01-1998 29-09-2000 31-08-2000 11-02-1999 12-05-1998 26-05-1998 30-09-1996



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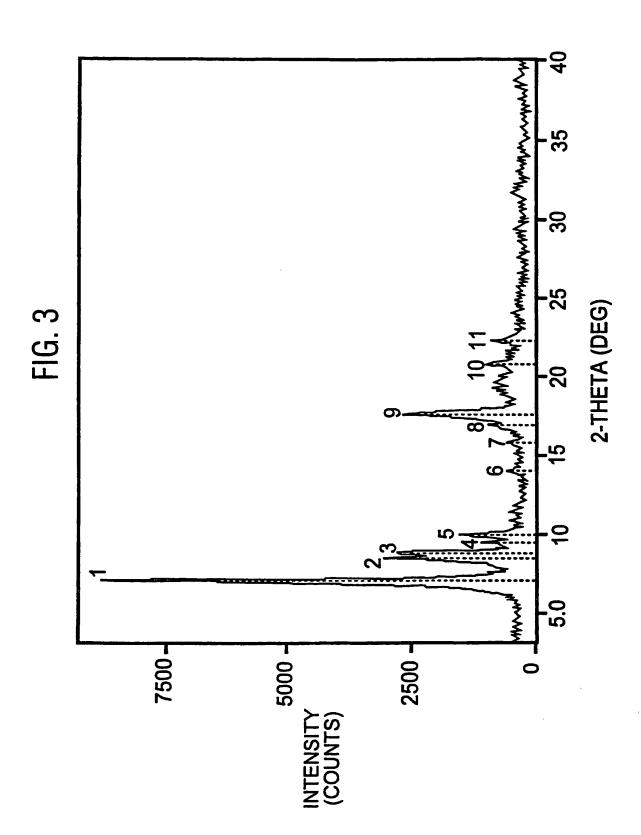
#	2-Theta	d(A)	Peak	P%	Area	Area%	FWHM
-	092.9	13.0648	5106	100.0	1497	100.0	0.234
7	8.183	10.7953	1743	34.1	435	29.1	0.200
က	8.560	10.3207	1866	36.5	543	36.3	0.233
4	9.239	9.5638	234	4.6	29	1.9	960.0
2	9.760	9.0546	972	19.0	220	14.7	0.181
9	10.569	8.3634	156	3.1	12	8.0	0.061
7	11.141	7.9353	178	3.5	29	1.9	0.130
<b>∞</b>	13.760	6.4304	792	5.2	46	3.1	0.138
6	15.599	5.6761	338	9.9	63	4.2	0.148
10	16.740	5.2917	433	8.5	64	4.3	0.118
11	17.420	5.0866	1890	37.0	689	46.0	0.291
12	20.639	4.3000	523	10.2	128	8.5	0.196
13	21.391	4.1505	188	3.7	20	1.3	0.085
14	22.139	4.0119	445	8.7	74	4.9	0.132
15	31.559	2.8326	270	5.3	24	1.6	0.070

1G. 1A



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#	2-Theta	d(A)	Peak	P%	Area	Area%	FWHIM
-	668.9	12.8028	13186	100.0	3025	100.0	0.184
7	8.261	10.6945	5221	39.6	931	30.8	0.143
m	8.838	6966.6	2057	15.6	482	15.9	0.187
4	11.061	7.9927	785	6.0	160	5.3	0.163
8	12.100	7.3086	1355	10.3	150	4.9	0.088
9	13.619	6.4964	450	3.4	8	2.9	0.157
7	17.677	5.0132	753	5.7	126	4.2	0.134
<b>∞</b>	18.180	4.8755	2011	15.3	588	19.4	0.234
6	20.840	4.2588	439	3.3	40	1.3	0.072
10	21.334	4.1615	427	3.2	<i>L</i> 9	2.2	0.125



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% FWHM	0 0.273	0 0.246	4 0.282	090.0	7 0.245	9 0.062	3 0.121	6 0.284	9 0.264	5 0.138	0 150
a Area%	9 100.0	2 26.0	2 26.4	5 0.9	6 12.7	6.0 9	8 1.3	3 7.6	9 25.9	1 2.5	7 3.8
6 Area	.0 2809	.9 732	.6 742	4.0 25	.1 356	4.0 26	3.0 38	7.3 213	.8 729	4.9 71	6.8 107
Peak P%	24 100.0	75 28.9	07 25.6	328 4.	1160 14.1	330 4.	244 3.	7 7.5	2206 26.8	407 4	9 583
d(A) Pe	12.6918 8224	10.5414 2375	10.1544 2107	9.4176 33	8.8906 11	6.3317 3	5.6120 2	5.2357 5	5.0521 22	4.2672 4	3.9902 5
2-Theta d	6.959 12.	8.381 10.	8.701 10.	9.383 9.	9.941 8.	13.975 6.	15.778 5.	16.920 5.	17.540 5.	20.799 4.	22.261 3.
# 2-1	1 6	2	3	4	5	6 13	7 15	8 16	9 17	10 20	11 22

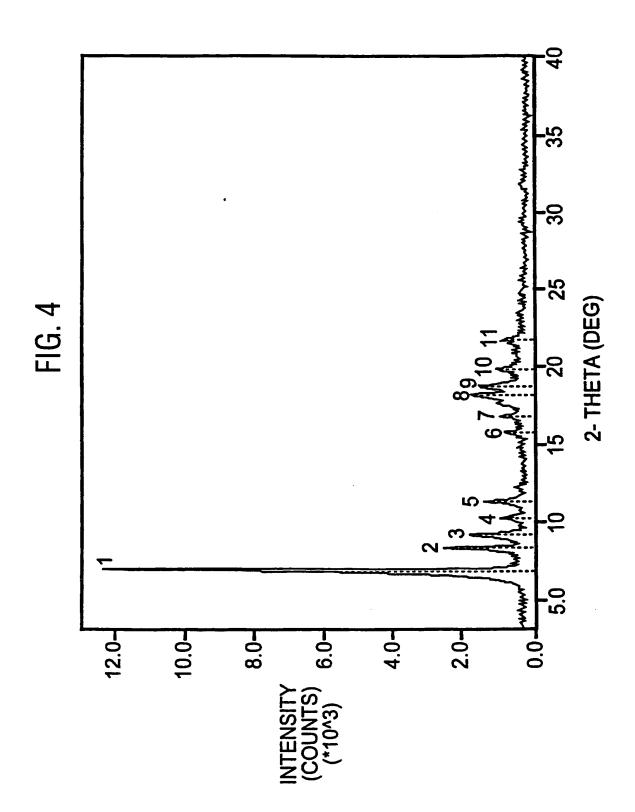
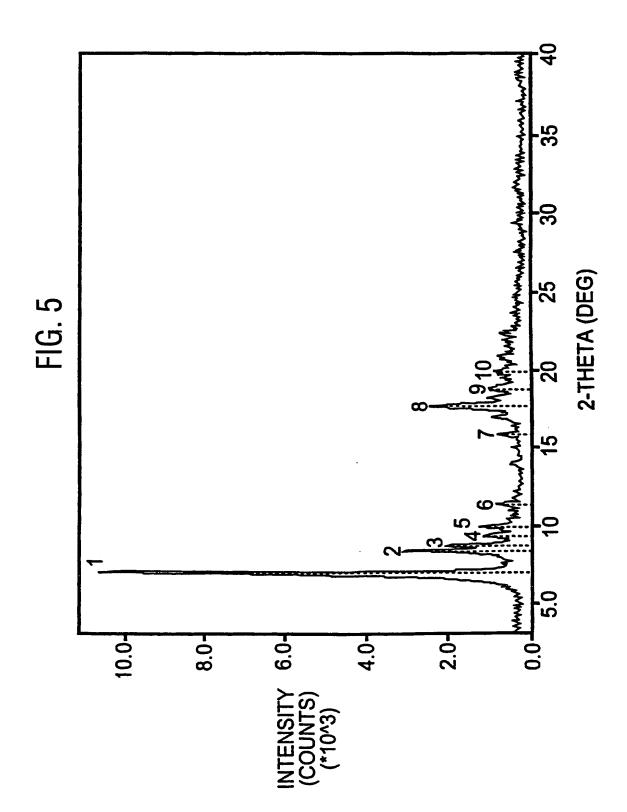


FIG. 4A

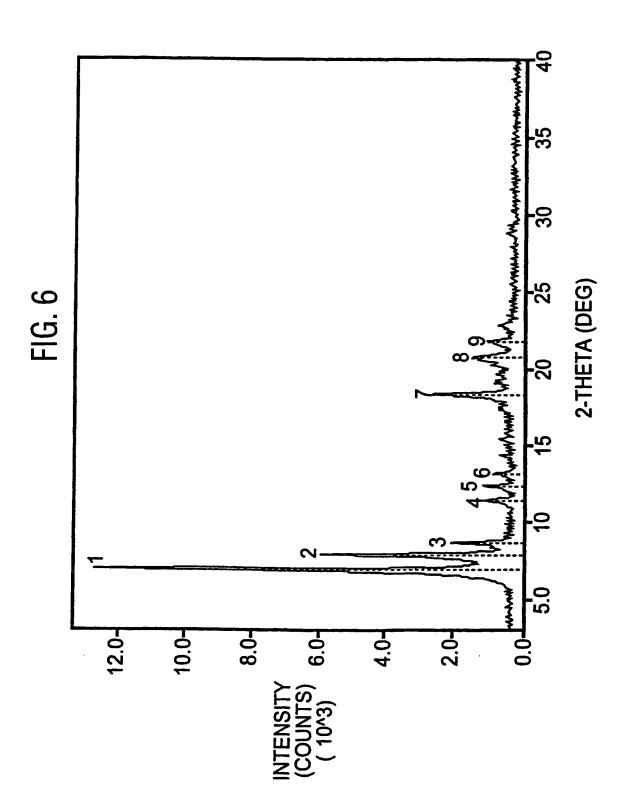
11991 100.0 2046 17.1	
17.1	2046 1438 632 1079 463
	<ul><li>(438)</li><li>(632)</li><li>(1079)</li><li>(463)</li></ul>
12.0	632 1079 463
5.3	1079
0.6	463
3.9	
3.6	432
10.5	1260
5.8	700
4.9	589
4.3	510



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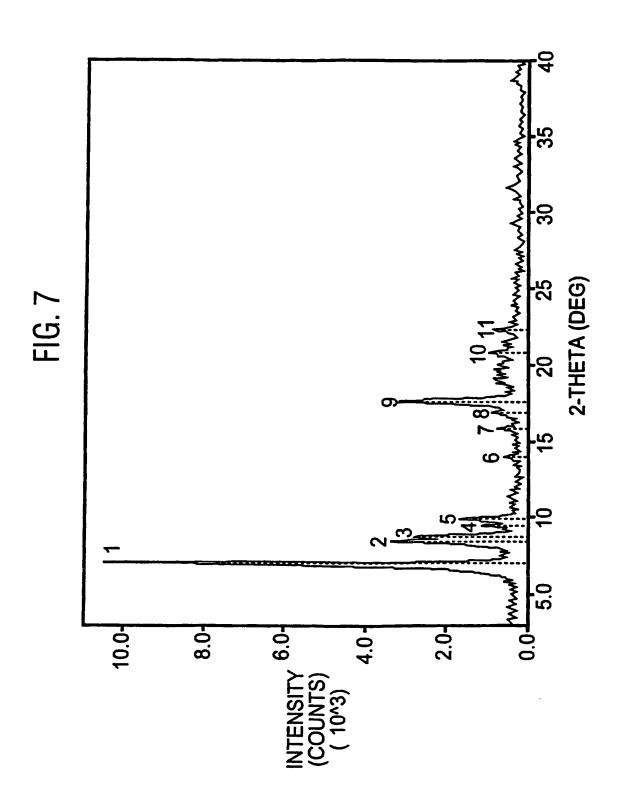
#	# 2-Theta	d(A)	Peak	P%	Area	Area%	FWHIM
-	6.901	12.7988	10206	100.0	2683	100.0	0.210
7	8.360	10.5679	2545	24.9	524	19.5	0.164
ю	8.680	10.1792	1459	14.3	359	13.4	0.197
4	9.279	9.5230	280	5.7	91	3.4	0.125
2	9.879	8.9456	794	7.8	143	5.3	0.143
9	11.321	7.8094	277	5.7	64	3.6	0.133
7	15.780	5.6113	523	5.1	95	3.5	0.144
<b>∞</b>	17.541	5.0519	1710	16.8	418	15.6	0.195
0	18.702	4.7408	459	4.5	116	4.3	0.201
10	19.877	4.4631	403	3.9	<i>L</i> 9	2.5	0.133

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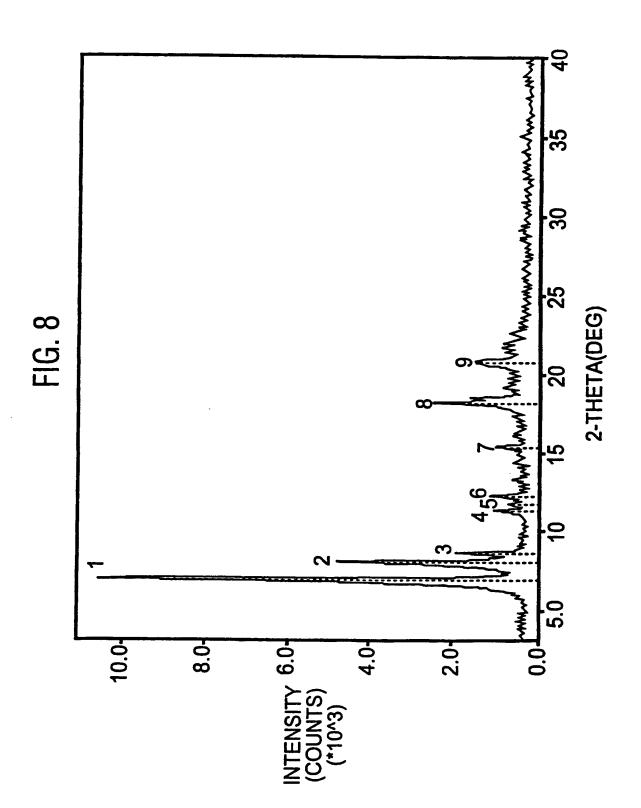
## 12/27

FWHM	0.226	0.186	0.167	0.146	0.135	0.057	0.245	0.269	0.203
Area%	100.0	32.0	10.2	4.0	3.6	1.0	17.1	8.0	4.2
Area	3495	1119	357	141	127	37	969	279	146
P%	100.0	38.9	13.8	6.2	6.1	4.2	15.7	2.9	4.6
Peak	12371	4815	1709	771	752	517	1945	828	573
d(A)	12.8025	11.2637	10.2009	7.7833	7.1900	6.7528	4.8540	4.2832	4.0847
2-Theta	6889	7.843	8.661	11.359	12.300	13.100	18.262	20.721	21.740
#	_	7	3	4	2	9	7	<b>∞</b>	6



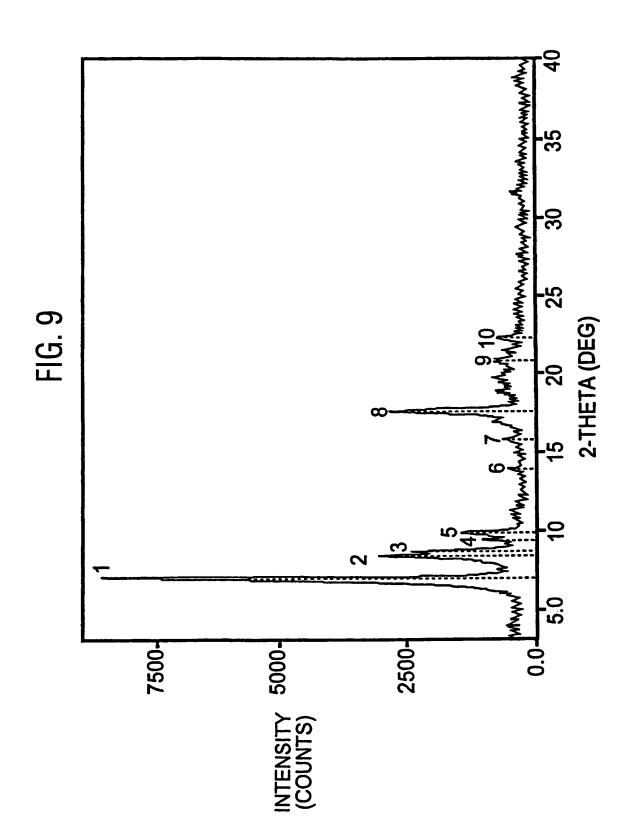
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FWHM	0.218	0.222	0.272	0.051	0.158	0.118	0.079	0.264	0.260	0.114	0.229
Area%	100.0	29.1	28.4	1.2	9.4	2.0	1.6	7.0	31.1	2.7	5.7
Area	2717	790	772	32	255	99	45	192	846	73	156
P%	100.0	28.6	22.7	4.9	12.9	3.7	4.5	5.8	26.1	5.1	5.4
Peak	0866	2850	2267	487	1288	374	450	280	2604	208	542
d(A)	12.7278	10.5414	10.2253	9.3815	8.9812	6.3476	5.6253	5.2539	5.0464	4.2787	3.9796
2-Theta	6.939	8.381	8.640	9.419	9.840	13.940	15.741	16.861	17.560	20.743	22.321
#		7	က	4	2	9	7	<b>∞</b>		10	11



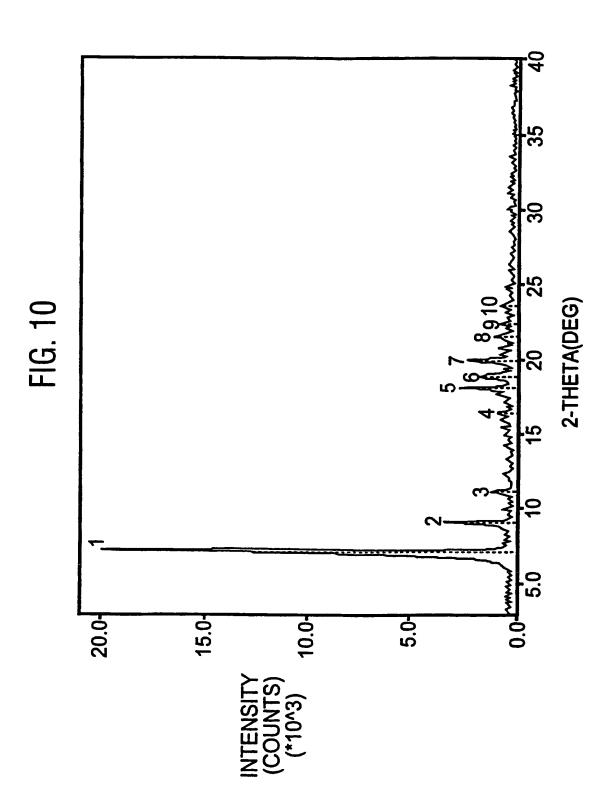
16/27

FWHIM	0.204	0.161	0.171	0.082	0.093	0.138	0.140	0.182	0.208
Area%	100.0	31.2	13.5	2.6	1.1	5.1	4.2	17.2	8.6
Area	2562	800	346	89	28	131	107	441	222
P%	100.0	39.7	16.1	9.9	2.4	9.7	6.1	19.3	8.5
Peak	10028	3984	1619	859	236	761	610	1937	853
d(A)	12.7674	11.0427	10.2506	7.7981	7.5459	7.2243	5.7557	4.8803	4.2713
2-Theta	6.918	8.000	8.619	11.338	11.718	12.241	15.382	18.162	20.779
#	-	7	m	4	2	9	7	<b>∞</b>	6



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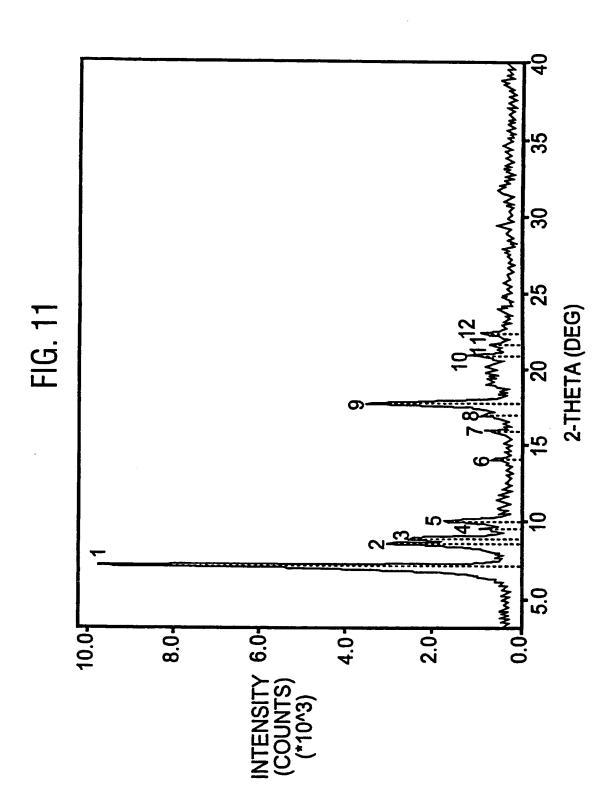
2-1	2-Theta	d(A)	Peak	<b>%</b>	Area	Area%	FWHIM
9	6.877	12.8422	8063	100.0	2195	100.0	0.218
∞	8.330	10.6062	2501	31.0	800	36.4	0.256
<b>&amp;</b>	8.581	10.2965	1898	23.5	514	23.4	0.217
O,	9.356	9.4446	432	5.4	45	2.0	0.082
5	9.799	9.0191	1064	13.2	275	12.5	0.207
$\Xi$	13.864	6.3821	293	3.6	28	2.6	0.158
1	15.721	5.6322	312	3.9	<i>L</i> 9	3.0	0.170
	17.480	5.0693	2458	30.5	868	40.9	0.292
7	20.818	4.2633	299	3.7	<i>L</i> 9	3.0	0.178
7	22.280	3.9869	416	5.2	106	4.8	0.202



#### 20/27

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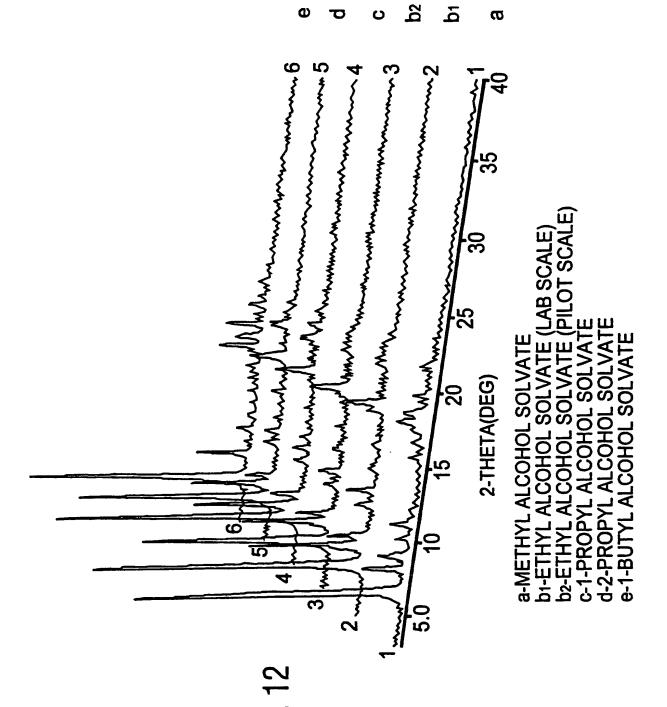
#	2-Theta	d(A)	Peak	P%	Area	Area%	FWHM
-	7.060	12.5101	19609	100.0	4796	100.0	0.196
7	9.078	9.7332	3027	15.4	292	11.8	0.150
m	11.100	7.9644	924	4.7	164	3.4	0.142
4	16.361	5.4135	554	2.8	92	1.6	0.109
\$	18.040	4.9133	2276	11.6	456	9.5	0.160
9	18.820	4.7112	1303	9.9	385	8.0	0.236
7	19.922	4.4532	1886	9.6	457	9.5	0.193
<b>∞</b>	21.560	4.1183	853	4.4	205	4.3	0.191
6	22.281	3.9867	343	1.7	37	0.8	0.086
10	23.521	3.7793	450	2.3	107	2.2	0.189

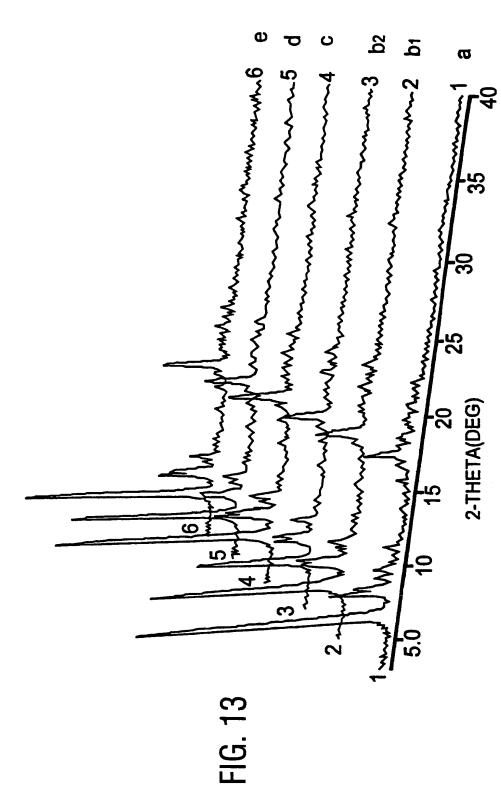


# FIG. 11A

1         7.018         12.5854         9344         100.0         2618         100.0         0.25           2         8.432         10.4775         2599         27.8         676         25.8         0.20           3         8.722         10.1302         2091         22.4         697         26.6         0.26           4         9.499         9.3030         378         4.0         33         1.2         0.06           5         9.980         8.8560         1243         13.3         337         12.9         0.01           6         14.000         6.3206         390         4.2         64         1.7         0.01           7         15.861         5.5830         550         5.9         46         1.7         0.06           8         16.881         5.2479         595         6.4         115         4.4         0.15           9         17.622         5.0287         3006         32.2         1053         40.2         0.28           10         20.918         4.2431         718         7.7         113         4.3         0.11           11         21.641         4.1031         316 <td< th=""><th>#</th><th>2-Theta</th><th>d(A)</th><th>Peak</th><th>P%</th><th>Area</th><th>Area%</th><th>FWHIM</th></td<>	#	2-Theta	d(A)	Peak	P%	Area	Area%	FWHIM
8.43210.4775259927.867625.88.72210.1302209122.469726.69.4999.30303784.0331.29.9808.8560124313.333712.914.0006.32063904.2641.716.8815.24795956.41154.417.6225.0287300632.2105340.220.9184.24317187.71134.321.6414.10313183.4441.722.3803.96935736.11445.5	-	7.018	12.5854	9344	100.0	2618	100.0	0.224
8.722       10.1302       2091       22.4       697       26.6         9.499       9.3030       378       4.0       33       1.2         9.980       8.8560       1243       13.3       337       12.9         14.000       6.3206       390       4.2       64       2.4         15.861       5.5830       550       4.6       1.7         16.881       5.2479       595       6.4       115       4.4         17.622       5.0287       3006       32.2       1053       40.2         20.918       4.2431       718       7.7       113       4.3         21.641       4.1031       318       3.4       44       1.7         22.380       3.9693       573       6.1       144       5.5	7	8.432	10.4775	2599	27.8	9/9	25.8	0.208
9.4999.30303784.0331.29.9808.8560124313.333712.914.0006.32063904.2642.415.8615.58305505.9461.716.8815.24795956.41154.417.6225.0287300632.2105340.220.9184.24317187.71134.321.6414.10313183.4441.722.3803.96935736.11445.5	m	8.722	10.1302	2091	22.4	<b>L69</b>	26.6	0.266
9.9808.8560124313.333712.914.0006.32063904.2642.415.8615.5830550461.716.8815.24795956.41154.417.6225.0287300632.2105340.220.9184.24317187.71134.321.6414.10313183.4441.722.3803.96935736.11445.5	4	9.499	9.3030	378	4.0	33	1.2	0.069
14.000       6.3206       390       4.2       64       2.4         15.861       5.5830       550       46       1.7         16.881       5.2479       595       6.4       115       4.4         17.622       5.0287       3006       32.2       1053       40.2         20.918       4.2431       718       7.7       113       4.3         21.641       4.1031       318       3.4       44       1.7         22.380       3.9693       573       6.1       144       5.5	8	9.980	8.8560	1243	13.3	337	12.9	0.217
15.861       5.5830       550       5.9       46       1.7         16.881       5.2479       595       6.4       115       4.4         17.622       5.0287       3006       32.2       1053       40.2         20.918       4.2431       718       7.7       113       4.3         21.641       4.1031       318       3.4       44       1.7         22.380       3.9693       573       6.1       144       5.5	9	14.000	6.3206	390	4.2	64	2.4	0.130
16.881       5.2479       595       6.4       115       4.4         17.622       5.0287       3006       32.2       1053       40.2         20.918       4.2431       718       7.7       113       4.3         21.641       4.1031       318       3.4       44       1.7         22.380       3.9693       573       6.1       144       5.5	7	15.861	5.5830	550	5.9	46	1.7	990.0
17.622       5.0287       3006       32.2       1053       40.2         20.918       4.2431       718       7.7       113       4.3         21.641       4.1031       318       3.4       44       1.7         22.380       3.9693       573       6.1       144       5.5	<b>∞</b>	16.881	5.2479	595	6.4	115	4.4	0.154
20.918       4.2431       718       7.7       113       4.3         21.641       4.1031       318       3.4       44       1.7         22.380       3.9693       573       6.1       144       5.5	6	17.622	5.0287	3006	32.2	1053	40.2	0.280
21.641     4.1031     318     3.4     44     1.7       22.380     3.9693     573     6.1     144     5.5	10	20.918	4.2431	718	7.7	113	4.3	0.126
22.380 3.9693 573 6.1 144 5.5	11	21.641	4.1031	318	3.4	44	1.7	0.110
	12	22.380	3.9693	573	6.1	144	5.5	0.201

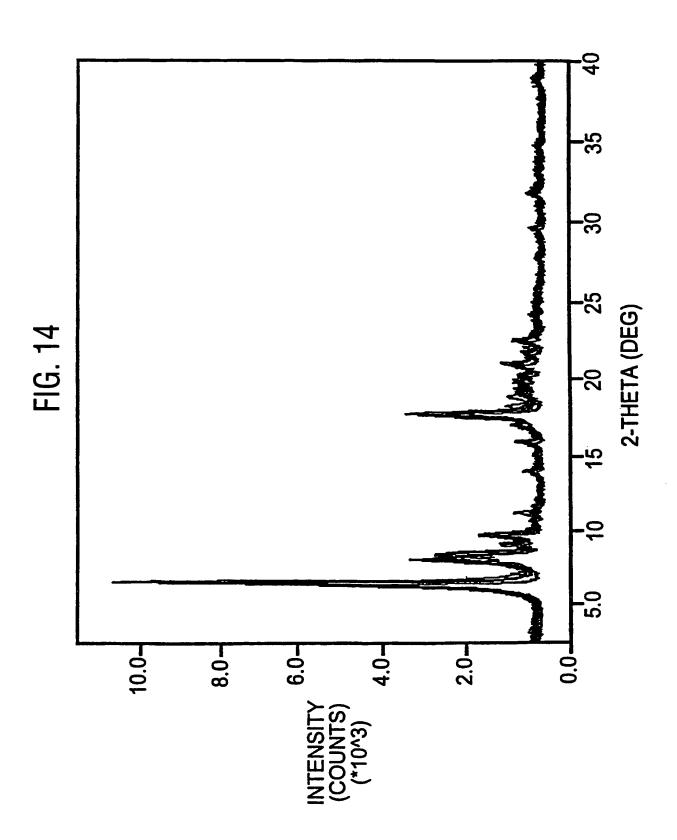
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(PILOT SCALE) (LAB SCA) - SOLVATE FREE CRYSTALLINE FORM FROM METHYI INE FORM FROM ETHY bz-SOLVEN

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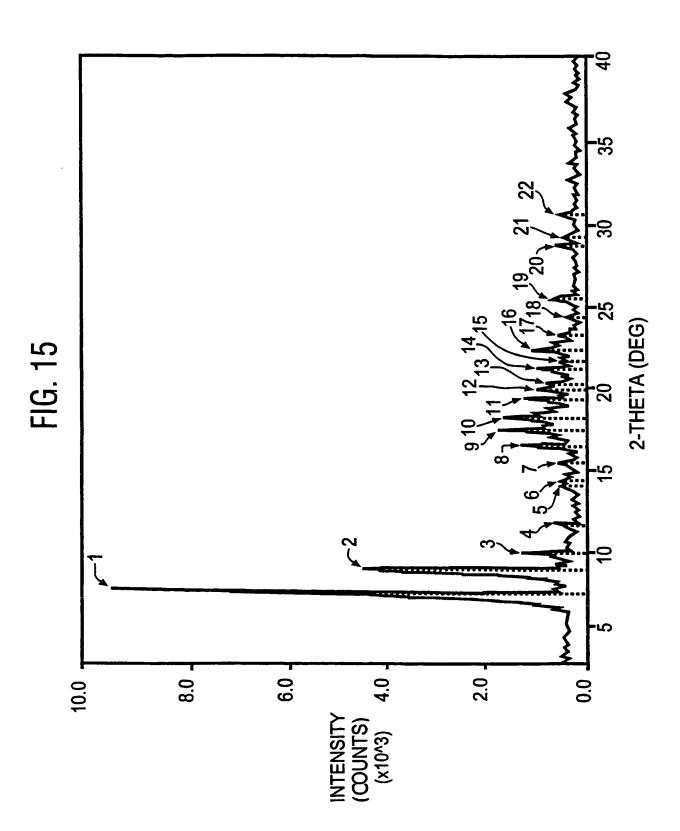




FIG. 15A

#	2-THETA	d(A)	PEAK	P%	AREA	AREA%	FWHM
1	7.259	12.1686	9283	100	2482	100	0.214
2	8.739	10.1100	4191	45.1	603	24.3	0.115
3	9.386	8.9628	967	10.4	161	6.5	0.133
4	11.659	7.5838	430	4.6	49	1.9	0.089
5	13.955	6.3408	305	3.3	58	2.3	0.151
6	14.220	6.2233	326	3.5	73	2.9	0.178
7	15.387	5.7537	278	3.0	19	0.7	0.053
8	16.461	5.3806	986	10.6	187	7.5	0.152
9	17.361	5.1039	1490	16.1	348	14.0	0.187
10	18.063	4.9069	1284	13.8	323	13.0	0.201
11	19.302	4.5947	871	9.4	166	6.7	0.152
12	19.862	4.4664	686	7.4	142	5.7	0.166
13	20.200	4.3923	457	4.9	103	4.1	0.179
14	21.178	4.1918	656	7.1	97	3.9	0.117
15	21.641	4.1031	167	1.8	6	0.2	0.029
16	22.300	3.9833	794	8.6	192	7.7	0.193
17	23.218	3.8278	247	2.7	23	0.9	0.071
18	24.100	3.6897	183	2.0	34	1.3	0.145
19	25.481	3.4928	487	5.2	141	5.7	0.231
20	28.800	3.0974	134	1.4	14	0.6	0.083
21	29.297	3.0459	259	2.8	28	1.1	0.084
22	30.700	2.9099	287	3.1	20	0.8	0.055